

D6 20. (Amended once) A composition of matter as defined in claim 15, wherein said solubilizing agent is selected from the group consisting of:

- 1) organic acids and organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

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D8 22. (Amended twice) A method of increasing the solubility of sertraline in an aqueous chloride ion-containing use environment, comprising administering said sertraline to said use environment in a composition of matter additionally comprising a solubilizing agent, wherein said sertraline is in the form of a highly soluble salt form having a solubility in pure water of greater than 10 mgA/mL.

29. (Amended once) A composition of matter as defined in claim 22, wherein said solubilizing agent is selected from the group consisting of:

- 1) organic acids and organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

Please add the following new claims:

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30. The composition of claim 1 wherein said highly soluble salt form of sertraline is selected from the group consisting of sertraline aspartate, sertraline acetate, and sertraline lactate.
 31. The composition of claim 10 wherein said highly soluble salt form of sertraline is selected from the group consisting of sertraline aspartate, sertraline acetate, and sertraline lactate.

32. The composition of claim 15 wherein said highly soluble salt form of sertraline is selected from the group consisting of sertraline aspartate, sertraline acetate, and sertraline lactate.

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cmt 33. The composition of claim 1 wherein said solubilizing agent is selected from the group consisting of adipic acid, erythorbic acid, itaconic acid, citric acid, ascorbic acid, aspartic acid, glutamic acid, and lactic acid.

34. The composition of claim 10 wherein said solubilizing agent is selected from the group consisting of adipic acid, erythorbic acid, itaconic acid, citric acid, ascorbic acid, aspartic acid, glutamic acid, and lactic acid.

35. The composition of claim 15 wherein said solubilizing agent is selected from the group consisting of adipic acid, erythorbic acid, itaconic acid, citric acid, ascorbic acid, aspartic acid, glutamic acid, and lactic acid.

36. The composition of claim 33 further comprising another solubilizer selected from the group consisting of

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers;
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

37. The composition of claim 34 further comprising another solubilizer selected from the group consisting of:

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers;

- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

38. The composition of claim 35 further comprising another solubilizer selected from the group consisting of

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers;
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

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39. A composition of matter comprising sertraline or a pharmaceutically acceptable salt form of sertraline and an amount of a solubilizing agent sufficient to produce a concentration of dissolved sertraline in a use environment containing chloride ions which is 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent, wherein said solubilizing agent has a solubility of at least 1 mg/ml in said use environment and wherein said solubilizing agent is an organic acid.

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Pharmaceutically acceptable salt form*

40. A composition of matter as defined in claim 39, wherein said use environment is the GI tract.

41. A composition of matter as defined in claim 39, wherein said use environment is an aqueous chloride ion-containing test medium.

42. A composition of matter as defined in claim 41, wherein said use environment is 0.075 M sodium chloride.

43. A composition of matter as defined in claim 39, which is an immediate release dosage form.

44. A composition of matter as defined in claim 39, which is a controlled release dosage form.

45. A composition of matter as defined in claim 39, further comprising another solubilizing

agent selected from:

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

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46. A composition of matter as defined in claim 42, wherein the amount of said solubilizing agent is sufficient to maintain, for at least 2 hours, the concentration of dissolved sertraline at a level which is at least 1.5 times higher than the concentration of sertraline produced by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent.

47. A composition as defined in claim 39, wherein said solubilizing agent is selected from malic acid, citric acid, erythorbic acid, adipic acid, maleic acid, aspartic acid, tartaric, and glutamic acid.

48. A composition of matter comprising sertraline or a pharmaceutically acceptable salt thereof and an amount of a solubilizing agent sufficient to produce and to maintain, for at least 2 hours in 0.075M sodium chloride, a concentration of dissolved sertraline which is at least 1.5 times higher than the concentration effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent, wherein said solubilizing agent has a solubility of at least 1 mg/ml in said use environment and wherein said solubilizing agent is an organic acid.

49. A composition of matter as defined in claim 48, which is an immediate release dosage form.

50. A composition of matter as defined in claim 48, which is a controlled release dosage form.

51. A composition of matter as defined in claim 48, further comprising another solubilizing agent selected from the group consisting of:

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;

- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;
- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers;
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

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52. A composition as defined in claim 48, wherein said solubilizing agent is selected from the group consisting of malic acid, citric acid, erythorbic acid, adipic acid, maleic acid, aspartic acid, tartaric, and glutamic acid.

53. A composition of matter comprising sertraline or a pharmaceutically acceptable salt thereof and an amount of a solubilizing agent sufficient to effect, *in vivo*, a C_{max} and/or an AUC which is greater by at least 10% than the C_{max} and/or AUC effected by a comparative composition of matter identical thereto but for the inclusion of said solubilizing agent, wherein said solubilizing agent has a solubility of at least 1 mg/ml in said use environment and wherein said solubilizing agent is an organic acid.

54. A composition as defined in claim 53, wherein said C_{max} and/or AUC effected by said solubilizing agent-containing composition is at least 15% higher than the corresponding C_{max} and/or AUC effected by said comparative composition.

55. A composition as defined in claim 53, wherein said C_{max} and/or AUC effected by said solubilizing agent-containing composition is at least 20% higher than the corresponding C_{max} and/or AUC effected by said comparative composition.

56. A composition of matter as defined in claim 53, which is an immediate release dosage form.

57. A composition of matter as defined in claim 53, which is a controlled release dosage form.

58. A composition of matter as defined in claim 53, further comprising another solubilizing agent selected from the group consisting of:

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glycerides;
- 4) glyceride derivatives;
- 5) polyethylene glycol esters;
- 6) polypropylene glycol esters;

- 7) polyhydric alcohol esters;
- 8) polyoxyethylene ethers;
- 9) sorbitan esters;
- 10) polyoxyethylene sorbitan esters; and
- 11) calcium salts.

59. A composition of matter as defined in claim 53, wherein said solubilizing agent is selected from the group consisting of malic acid, citric acid, erythorbic acid, adipic acid, maleic acid, aspartic acid, tartaric, and glutamic acid.

60. A method of increasing the solubility of sertraline in an aqueous chloride ion-containing use environment, comprising administering said sertraline to said use environment in a composition of matter additionally comprising a solubilizing agent, wherein said solubilizing agent has a solubility of at least 1 mg/ml in said use environment and wherein said solubilizing agent is an organic acid.

61. A method as defined in claim 60, wherein the concentration of dissolved sertraline in said use environment also containing said solubilizer is at least 1.5-fold higher than the concentration of sertraline effected by a comparative composition identical to said solubilizing agent-containing composition except for the inclusion of said solubilizing agent.

62. A method as defined in claim 60, wherein said use environment is the GI tract.

63. A method as defined in claim 60, wherein said use environment is an aqueous chloride ion-containing test medium.

64. A method as defined in claim 63, wherein said medium is 0.075M sodium chloride.

65. A method as defined in claim 60, wherein said composition of matter is in the form of an immediate release dosage form.

66. A method as defined in claim 60, wherein said composition of matter is in the form of a controlled release dosage form.

67. A method as defined in claim 60, further comprising another solubilizing agent selected from the group consisting of:

- 1) organic acid salts;
- 2) partial glycerides;
- 3) glyccrides;